Environmental Assessment

FCN 001108

1. This environmental assessment (EA) concerns the proposed use of the FCS as a biocide preservative in aqueous latex/silicone formulations used in coatings on metal substrates complying with 21 CFR 175.300 and on polypropylene (PP) sheets complying with 21 CFR 175.320. Much of this information in this assessment relies on the EAs for FCNs 597 and 835 where the use conditions for the identical FCS were similar. A FIFRA label was submitted but it did not authorize the use of the FCS for the same use and use level. Thus, this EA is provided in lieu of an accepted FIFRA label.

2. **Date:** July 26, 2011

3. **Name of Notifier:** Lanxess Corporation

4. **Address:** 111 RIDC Park West Dr., Pittsburgh, PA 15275-1112
   All communications on this matter are to be agent/consultant for Lanxess:

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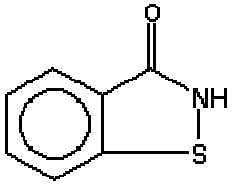
5. **Description of the Proposed Action**
   The action requested in this Food Contact Notification (FCN) is the establishment of a clearance to permit the use of 1, 2- benzisothiazol-3(2H)-one (BIT) biocide for use at a level not to exceed 5 wt-% of the preservative formulation which may be added to the latex/silicone formulations at a level not to exceed 0.3 wt%. Metal articles and polypropylene coatings containing the FCS may not exceed an applied coating rate of 7.74 mg/ sq in.

   The Notifier does not intend to produce finished food-contact articles, such as metal articles, polypropylene sheets, or other finished articles that may be used in contact with food that contain the subject biocide. Instead, BIT will be used in preservative formulations (alone or in combination with other biocides) to preserve aqueous preparations of latex/silcone to prepare coatings for food contact articles. BIT will be sold to manufacturers of other finished articles or manufacturers of formulations used in the finished articles.

Disposal of the food contact substance is expected to occur at locations where the metal articles or PP sheets are used with them being ultimately deposited in municipal solid waste landfills, or combusted in municipal waste combustors or commercial industrial solid waste incinerators.

6. Identification of Substance that Is the Subject of the Proposed Action

The additive that is the subject of this Notification is 1, 2- benzisothiazol-3(2H)-one
CAS Reg. No.: 2634-33-5
Molecular weight: 151.18
Molecular formula: C7H5NOS
Structural formula:



7. Introduction of Substances into the Environment

Under 21 C.F.R. 25.40(a), an environmental assessment ordinarily should focus on relevant environmental issues relating to the use and disposal from use rather than the production of FDA-regulated articles. Information available to the Notifier does not suggest that there are any extraordinary circumstances in this case indicative of any adverse environmental impact as a result of the manufacture of BIT. Consequently, information on the manufacturing site and compliance with relevant emissions requirements is not provided here. However, it should be noted that large quantities of the FCS are in production around the world for many biocide uses. The use proposed by this FCN utilises only a very small percentage of the FCS produced. Little or no introduction of the FCS into the environment will result from its production and use because this substance is almost completely incorporated into the coatings on metal articles or PP sheets. Essentially all of the FCS is expected to remain with the metal articles or PP sheets throughout their use.

Based on migration estimates used to demonstrate human safety of the proposed use and reported elsewhere in the FCN, we expect only very low levels of the FCS to leach or migrate from the metal articles or polypropylene sheets disposed of in landfills (see Section 9). Moreover, even if a very small amount of the FCS were to migrate from the articles or PP sheets which are in landfills, we expect extremely low quantities to actually enter the environment. This finding is based on the regulations of the U.S. Environmental Protection Agency (EPA) governing municipal solid waste landfills. The Environmental Protection Agency's regulations require new municipal solid waste landfill units and lateral expansions of existing units to have composite

liners and leachate collection systems to prevent leachate from entering ground and surface water and to have groundwater monitoring systems. Although owners and operators of existing active municipal solid waste landfills that were constructed before October 9, 1993 are not required to retrofit liners and leachate collection systems, they are required to monitor groundwater and to take corrective action as appropriate.

New food contact materials generally comprise a small fraction of the overall amount of waste combusted in the United States. Therefore, we believe that the combustion products from new food contact materials usually will not alter significantly the emissions from municipal waste combustors or commercial industrial solid waste incinerators and that any such emissions are governed by EPA's regulations on combustors in 40 CFR Part 60. This also would be the case for metal articles or polypropylene sheets manufactured using BIT as no increase in the annual market volume of these articles or sheets used for food handling is expected as a result of the proposed use of BIT becoming effective. The reason that no increase is expected in the annual market volume of metal articles or sheets used for food handling is that BIT does not impart any benefical effect to the final metal article or polypropylene sheet but merely preserves the liquid latex used in the manufacture of metal articles or PP sheets.

8. Fate of Emitted Substances in the Environment

Information is provided on the fate of substances released into the environment as the result of use and disposal of the metal articles or PP sheets containing BIT. This is done even though as discussed under format Item 7 and 9, only very small quantities of the substance, if any, will be introduced into the environment from its use and disposal. Therefore, we do not expect the use and disposal of BIT-containing metal articles or PP sheets to threaten a violation of applicable laws and regulations, e.g., EPA's regulations in 40 CFR Parts 60 and 258**.**

USEPA has reviewed the available information on properties of BIT that relate to its environmental fate and their summary follows (EPA, 2005):

> The environmental fate assessment for 1,2-benzisothiazolin-3-one was based on limited information; data were only available for hydrolysis, aerobic soil metabolism, and adsorption/desorption. These data indicate that 1,2-benzisothiazolin-3-one is hydrolytically stable (half-life > 30 days), but breaks down fairly quickly in aerobic soils (half-life < 24 hours in sandy loam soil). 1,2-Benzisothiazolin-3-one shows moderate to strong binding to soils, with adsorption Kd values estimated to be between 1.24 and 9.56. If used outdoors, 1,2-benzisothiazolin-3-one may possibly move with soil during rainfall events and potentially reach surface waters. However, it breaks down aerobically on the surface soils. Since it has a moderate binding potential to soils, it is not likely to migrate into the ground and there is low potential for ground water contamination. Furthermore, with a Kow value of 20 at 25°C, 1,2-benzisothiazolin-3-one is unlikely to bioaccumulate in aquatic organisms.

Additional fate studies were completed by Covance Laboratories Ltd., Rohm and Haas Company, RCC Ltd., and Wildlife International Ltd. after the above EPA study

was published. A photodegradation study in sterile, aqueous solutions was conducted by Covance Labs. It was found that photolysis could account for 100% degradation over 30 days, and that BIT "photodegraded very rapidly" in buffer solutions at pH 5, 7, and 9. At pH 7, 90% of the BIT degraded in 2.4 hours.

Another study was conducted by RCC to determine BIT's ready biodegradability in a 28-day Modified Sturm Test. It was found that BIT was not biodegradable under the test conditions within the 28-day exposure period. However, BIT was found to have no inhibitory effect on the activity of activated sludge microorganisms at the tested concentration of 18 mg/L. In another study by RCC it was determined that BIT was not inherently biodegradable in a manometric respirometry test over 28 days. A tropospheric phototransformation test was conducted by Rohm and Haas. BIT was found to have a short half-life of 10.3 hours and is expected to be quickly photodegraded in the troposphere. Potential metabolites were also reactive towards photodegradation with half-lives of from 5 to 237 hours. Thus, due to its very small annual production , the effect of BIT on global warming is negligible.

Two tests were completed by Wildlife International on transformation activity of soil microorganisms. It was found that any long-term effects (over a 28-day period) of BIT on carbon or nitrogen transformation activity of soil microorganisms in aerobic surface soils were minimal. Thus, there is little or no interference by BIT with these biochemical processes that would ultimately interfere with nutrient cycling and eventually alter soil fertility.

9. Environmental Effects of Released Substances

USEPA has reviewed the available data on the toxicity of BIT to species that are viewed as sentinels or indicator species for determining potential environmental effects and their summary follows (EPA, 2005):

> The available ecological effects data for 1,2-benzisothiazolin-3-one are somewhat limited. Based on toxicity information, 1,2-benzisothiazolin-3-one displays low to moderate toxicity to birds and mammals. It is moderately toxic to freshwater fish and invertebrates, slightly toxic to marine/estuarine fish, and highly toxic to marine/estuarine invertebtrates.

Additional aquatic, sediment, and terrestrial toxicity tests were conducted by Wildlife International Ltd. with other test organisms after the above EPA analysis was published. Toxicty test data for various aquatic and terrestrial test organisms are listed and examined more closely in the table below.

Aquatic and Terrestrial Toxicity Test Results for 1,2-benzisothiazolin-3-one

Toxicity Test	Test Endpoint	Toxiciity/ Hazard Ranking
Daphnia magna (water flea) 21-day Flow-Through Life-Cycle	MATC 1.9 mg a.i./L EC50 (reproduction) >3.8 mg a.i./L	Moderate chronic toxicity and hazard to fresh water invertebrates
Pseudokirchneriella subcapitata (fresh water green alga) 96-hr acute/chronic	EC50 0.38-0.98 mg a.i./L; NOAEC 0.32-0.80 mg a.i./L	High to moderate acute/chronic toxicity and hazard to algae
Daphnia magna 48-hr Flow-Through acute	EC50 3.7 mg a.i./L	Moderate acute toxicity and hazard to fresh water invertebrates
Six Terrestrial Plant Species: 21-day Seedling Emergence	EC50s ranged from 18.4-166 mg a.i./L	Moderate to low toxicity and hazard to terrestrial plants
Oncorhynchus mykiss (Rainbow Trout) 96-hr Flow-Through	LC50 1.9 mg a.i./L	Moderate acute toxicity and hazard to fish
Pimephales promelas 33-day Early Life-Stage	MATC (growth) 0.41 mg a.i./L	Moderate chronic toxicity and hazard to fish
Chironomus riparius Spiked sediment toxicity, 28-day prolonged test	96 hr EC50 52 mg a.i./L; NOEC 25 mg a.i./L	Moderate toxicity and hazard to sediment-dwelling aquatic organisms
Chironomus tentans (=s dilutus) 10-day Survival and Growth	96 hr EC50 >100 mg a.i./L; NOEC 50 mg a.i./L	Low toxicity and hazard to sediment-dwelling aquatic organisms
Eisenia foetida (earthworm) 7-day acute test	LC50 278 mg a.i./L	Low toxicity and hazard to terrestrial invertebrates

All of these tests were conducted by Wildlife International Ltd., Easton, MD.

Estimates and information are provided on the effect of substances released into the environment as the result of use and disposal of the BIT-containing metal articles or PP sheets. It is not certain how much of the FCS will migrate or be released into the environment through use and disposal, but this quantity is expected to be very small. Based on the physicochemical properties of the FCS and the intended use of the substance as a component of metal can coatings and coatings on PP sheets, it is believed that a substantial amount of the FCS will migrate into foods, thus limiting additional migration of BIT into the environment. The FCN migration values were calculated under the worst-case assumption that 100% of the FCS would migrate into foods. Dietary concentrations calculated from both metal article and polypropylene sheet uses totaled 24.3 ppb.

Available toxicity effects values for this FCS are well documented, and aquatic values range from slight (to marine/estuarine fish), to moderate (to fresh water fish and invertebrates), and to high (to marine/estuarine invertebrates) (EPA, 2005). The table above presents additional, more recent toxicity test results that indicate moderate to high toxicity to algae, low or moderate toxicity to sediment organisms and terrestrial plants, and low toxicity to terrestrial organisms. In hazard ranking systems used to compare toxicity values (see for example, Smrchek and Zeeman, 1998), slight often means 1000 ppm or higher, low means 100 to 1000 ppm, moderate means greater than 1 ppm up to 100 ppm, and high means less than or equal to 1 ppm.

The Environmental Introduction Concentration (EIC) can be now estimated. It is assumed that all BIT from these surface coatings migrates into the environment at the sites of disposal, in landfills. It is expected that the EIC will be considerably lower than the lowest or most toxic environmental effects toxicity value (0.38 mg a.i./L EC50 value for green algae). This conclusion is based on several reasons:

1. BIT will be present in very low concentrations because this FCN is for a minor use when compared to the total BIT market.
2. BIT will be used in very small quantitites, that is it will be only 5% of the preservative formulation, and this formulation is added to the latex/silicone preparation (the coating) at a 0.3% level.
3. Fate characteristics of BIT will limit introduction and movement in the landfill environment. BIT degrades fairly quickly in aerobic soils (half- life is less than 24 hrs in sandy loam soil). BIT will bind to soils, with availability and migration being limited (Kd values estimated to be between 1.24 and 9.56). Groundwater contamination is limited. BIT may move with soil during rainfall events, but toxicity of BIT was found to be low to terrestrial invertebrates and plants, and to sediment-dwelling aquatic organisms. However, BIT will be confined to landfills, and the FCS photodegrades very rapidly in aqueous solutions.

Thus, the levels of BIT present in the environment will likely be very low, certainly in the low ppb range. Furthermore, it is expected that only very small quantities of the FCS will be introduced into the environment from use and disposal. It is concluded that the use and disposal of metal articles or PP sheets containing BIT are not expected to threaten a violation of applicable laws and regulations, e.g., EPA's regulations in 40 CFR Parts 60 and 258.

10. Use of Resources and Energy

BIT is intended to preserve latex/silicone emulsions added to coatings for food-contact metal articles and polypropylene sheets used in the the food processing industry. Thus, there is essentially no effect on the use of natural resources and energy or the quantity of metal articles or PP sheets, themselves, produced using biocides. The use of BIT will not increase the demand for metal articles or PP sheets. Therefore there will be no increase in utilization of natural resources.

Metal articles containing BIT are recovered for recycling. EPA determined that in 2009, 66.2% of steel (mostly cans) was recovered (EPA, 2010). However, polypropylene sheets are disposed of by means of sanitary landfill and incineration, and are not recycled. PP sheets containing BIT are expected to be disposed of according to the same patterns when they are used in place of PP sheets that do not contain BIT. Thus, there will be no impact of PP sheets on current or future recycling programs. Metal articles containing BIT may impact current or future recycling programs because these articles add to the volume of generated products and the quantity of recycled metals.

11. Mitigation Measures

As shown above, no significant adverse environmental impacts are expected to result from the use and disposal of metal articles or polypropylene sheets with coatings containing BIT. This is primarily due to the minute levels of BIT leaching or migrating from these articles and sheets, the insignificant impact on environmental concentrations of combustion products of BIT in disposed PP sheets, and the fact that the use of BIT in metal articles and PP sheets is small compared to use of BIT in other products. Therefore, the use of BIT as proposed is not reasonably expected to result in any new environmental problems requiring mitigation measures of any kind.

12. Alternatives to the Proposed Action

No potential adverse environmental effects are identified herein which would necessitate alternative actions to that proposed in this Notification. The alternative of not approving the action proposed herein would be to not use BIT to preserve latex/silicone formulations. The alternative action would have adverse environmental consequences because a certain amount of spoiled latex would require disposal in some manner were no BIT used.

Using a substitute biocide as a latex/silicone preservative may cause adverse environmental consequences and risk unique to this substitute. In addition, the substitute may be more toxic or bioavailable than BIT.

BIT is not expected to enter the environment in more than minute quantities from the use and disposal of finished food-contact metal articles or PP sheets. Also, there is an absence of any significant environmental hazard and impact that would result from the use of BIT. Therefore, the clearance of the use of BIT as described herein by allowing this Notification to become effective, is warranted and environmentally safe in every respect.

13. Preparers

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14. Certification

Both the undersigned official/preparer and EA preparer certify that the information provided herein is true, accurate, and complete to the best of our knowledge.

July 26, 2011

[redacted]

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Consultant to the Lanxess Corporation

[redacted]

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References

EPA, 2005. Reregistration Eligibility Decision (RED) for Benzisothiazoline-3-one (BIT). Environmental Protection Agency, September 29, 2005.

EPA, 2010. Municipal Solid Waste in the United States: 2009 Facts and Figures. Environmental Protection Agency, December 2010.

Smrchek, J.C. and Zeeman, M.G. 1998. Assessing risks to ecological systems from chemicals. In: *Handbook of Environmental Risk Assessment and Management,* P. Calow (ed.), Chapter 3, pp. 24-90. Blackwell Science Ltd., Oxford, UK.

Attachments

A product MSDS for BIT-85 is attached.